
A SHORT
INTRODUCTION
TO THE
RULES AND
REGULATIONS
GOVERNING
CHEMICAL
SAFETY
IN EUROPE



The regulatory landscape of chemical safety

The EU has extensive legislative measures in place to protect our health and environment. Over the past 15 years, regulations governing the use of substances and products and regulations protecting health and the environment have been substantially reviewed - leading, in particular, to the adoption of the REACH Regulation and the Regulation on the Classification, Labelling and Packaging (CLP) of chemical substances.

The European chemical industry works within this EU regulatory framework, ensuring the safe use of chemicals through an approach based on the identification of their hazardous properties and on the management of associated risks, if any.

These regulations make companies responsible for the safety of chemicals they use and place on the market. Moreover, a number of voluntary industry initiatives going beyond these regulations further enhance their scope. The whole industry, from producers to users, is thus committed to ensuring that people and the environment are not harmed by their products.

Altogether, this ensures that people and the environment are not exposed to chemicals at levels that have been shown to be harmful.

- If there were clear evidence showing that a substance is causing harm, then steps would have already been taken to restrict its use or to substitute it.
- Where there is evidence that a substance can harm people or the environment because of its intrinsic properties, appropriate restrictions are imposed to ensure that such harm does not materialise.
- Where there is some evidence to suggest that a substance might produce serious harm to health or the environment, precautionary measures, proportionate to the level of risk, will be adopted.

This evidence-based approach guarantees public health and protection of the environment, while allowing society to benefit from the safe use of chemicals.

The main features of the chemical regulations

The centrepiece of EU chemicals legislation is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which was adopted in 2006. Under REACH, companies are required to register the chemicals they produce, import or use and to provide sufficient evidence to enable the competent authority (The European Chemicals Agency or ECHA) to evaluate them and determine whether and how they can be used safely. The use of substances of very high concern (SVHC) requires specific authorisation, which may involve restrictions on particular uses or conditions of use that are demonstrated to be safe, and which may impose an obligation on companies to seek safer alternatives.

The Classification, Labelling and Packaging Regulation (CLP), adopted in 2008, ensures that the information concerning the safe use of chemicals, and the potential risks of misuse, are clearly communicated to workers and consumers through harmonised classification and labelling systems.

Other key regulations dealing with chemical safety

- The Biocidal Product Regulation (BPR), adopted in 2012, requires companies to provide extensive evidence regarding the properties of substances before they can be authorised for use as biocidal products that protect against harmful organisms, pests and bacteria.
- The Plant Protection Products Regulation (PPPR), adopted in 2009, imposes a similar obligation on companies seeking authorisation for use of specific chemicals as pesticides.
- The Prior Informed Consent Regulation (PIC), adopted in 2012, governs the import and export of hazardous chemicals. It places obligations on companies wishing to export these chemicals to non-EU countries.

Besides these regulations, there are:

- Regulations restricting the use of substances in various sectors, for example, the Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS), the Cosmetics Regulation, the Food Contact Materials Regulation, and the Toys Safety Directive.
- Various regulations imposing controls and specific exposure limit values in occupational health and safety applicable at EU and Member State levels.
- Substance-specific limit values or indicative values for the level of substances present in water/drinking water, air and soil.
- Specific transport packaging and waste management regulations.

...and many more.

Navigating the maze

To facilitate access to key regulatory information on a particular substance, the European Chemicals Agency (ECHA) has created a database containing information about substances registered under REACH, notified under CLP and/or registered under BPR. However, this database does not cover the whole body of EU regulations on chemicals in the EU. Nor does it cover other regulations in the Member States.

Cefic is therefore calling on the EU to create a central European substance-regulation navigator, which would enable someone to establish, for any substance:

- The regulations applicable to that substance and/or particular uses of that substance.
- What information relating to that substance is publicly available, at European or national level.

Beyond regulation: industry's voluntary initiatives

The European chemical industry works closely with the authorities to ensure that public health and the environment are protected.

Beyond this regulatory framework, the chemical industry is continuously seeking to better ensure that its products can be and are used safely.

Voluntary industry programmes, such as Responsible Care, go beyond regulation in search for safer and more sustainable products and processes. This is an international initiative, forming an essential part of the chemical industry contribution to the United Nations' Strategic Approach to International Chemicals Management (SAICM).

The Long-range Research Initiative (LRI) supports research projects that lead to increased knowledge of complex issues like those related to nanomaterials or endocrine disruptors, and informs the decision making process on how to handle chemicals safely.

General enquiries
safety@cefic.be
www.cefic.org

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of 29,000 large, medium and small chemical companies in Europe, which provide 1.2 million jobs and account for 17% of world chemical production.

Cefic members form one of the most active networks of the business community, complemented by partnerships with industry associations representing various sectors in the value chain.

A full list of our members is available on the Cefic website: www.cefic.org/About-us/Our-members

Cefic is an active member of the International Council of Chemical Associations (ICCA), which represents chemical manufacturers and producers all over the world and seeks to strengthen existing cooperation with global organisations such as UNEP and the OECD to improve chemicals management worldwide.





Chemistry making a world of difference

European Chemical Industry Council - Cefic aisbl

Avenue E. van Nieuwenhuysse 4 B-1160 Brussels Belgium

Tel. +32.2.676.72.11

www.cefic.org